

PCT

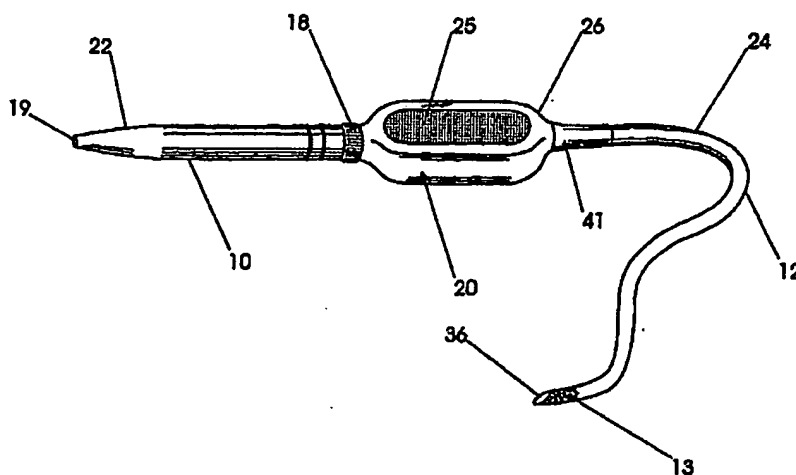
WORLD INTELLECTUAL PROPERTY ORGANIZATION
International Bureau



INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

(51) International Patent Classification 6 : A61M 39/02, 39/10		A1	(11) International Publication Number: WO 98/34676
		(43) International Publication Date: 13 August 1998 (13.08.98)	
(21) International Application Number: PCT/US98/01939		(81) Designated States: AL, AM, AT, AU, AZ, BA, BB, BG, BR, BY, CA, CH, CN, CZ, DE, DK, EE, ES, FI, GB, GE, GM, GW, HU, ID, IL, IS, JP, KE, KG, KP, KR, KZ, LC, LK, LR, LS, LT, LU, LV, MD, MG, MK, MN, MW, MX, NO, NZ, PL, PT, RO, RU, SD, SE, SG, SI, SK, TJ, TM, TR, TT, UA, UG, UZ, VN, ARIPO patent (GH, GM, KE, LS, MW, SD, SZ, UG, ZW), Eurasian patent (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), European patent (AT, BE, CH, DE, DK, ES, FI, FR, GB, GR, IE, IT, LU, MC, NL, PT, SE), OAPI patent (BF, BJ, CF, CG, CI, CM, GA, GN, ML, MR, NE, SN, TD, TG).	
(22) International Filing Date: 3 February 1998 (03.02.98)			
(30) Priority Data: 60/037,094 7 February 1997 (07.02.97) US 08/835,316 7 April 1997 (07.04.97) US			
(71)(72) Applicant and Inventor: SQUITIERI, Rafael, P. [US/US]; Apartment 8A, 320 South Street, Morristown, NJ 07960 (US).			
(74) Agents: DALY, Christopher, S. et al.; Nutter, McClen- nen & Fish, LLP, One International Place, Boston, MA 02110-2699 (US).		Published With international search report.	

(54) Title: VASCULAR ACCESS SYSTEMS FOR HEMODIALYSIS



(57) Abstract

A hemodialysis and vascular access system comprises a subcutaneous composite PTFE Silastic arteriovenous fistula utilizing an indwelling silastic venous end (12) which can be inserted percutaneously and a PTFE arterial end (10) which is anastomosed to an artery. Percutaneous access is then gained by direct puncture into a unique "needle receiving" site having a tubular passage (16) within a metal or plastic body (26) and a silicone upper surface (25) through which a needle is inserted to access the flow within the system. In an alternate embodiment without "needle sites", access may be gained by placing needles directly into the system i.e. the PTFE. The invention proposes an arterialized indwelling venous catheter where blood flows from an artery through the system and is returned to the venous system via an arrangement wherein the outflow openings are distinct and distant from the site where the system enters the vein. The site of blood returns to the venous system is not directly fixed to the venous wall but is free floating within the venous system. This system provides a hemodialysis and venous access graft which has superior longevity and performance, is easier to implant and is much more user friendly.

FOR THE PURPOSES OF INFORMATION ONLY

Codes used to identify States party to the PCT on the front pages of pamphlets publishing international applications under the PCT.

AL	Albania	ES	Spain	LS	Lesotho	SI	Slovenia
AM	Armenia	FI	Finland	LT	Lithuania	SK	Slovakia
AT	Austria	FR	France	LU	Luxembourg	SN	Senegal
AU	Australia	GA	Gabon	LV	Latvia	SZ	Swaziland
AZ	Azerbaijan	GB	United Kingdom	MC	Monaco	TD	Chad
BA	Bosnia and Herzegovina	GE	Georgia	MD	Republic of Moldova	TG	Togo
BB	Barbados	GH	Ghana	MG	Madagascar	TJ	Tajikistan
BE	Belgium	GN	Guinea	MK	The former Yugoslav Republic of Macedonia	TM	Turkmenistan
BF	Burkina Faso	GR	Greece	ML	Mali	TR	Turkey
BG	Bulgaria	HU	Hungary	MN	Mongolia	TT	Trinidad and Tobago
BJ	Benin	IE	Ireland	MR	Mauritania	UA	Ukraine
BR	Brazil	IL	Israel	MW	Malawi	UG	Uganda
BY	Belarus	IS	Iceland	MX	Mexico	US	United States of America
CA	Canada	IT	Italy	NE	Niger	UZ	Uzbekistan
CF	Central African Republic	JP	Japan	NL	Netherlands	VN	Viet Nam
CG	Congo	KE	Kenya	NO	Norway	YU	Yugoslavia
CH	Switzerland	KG	Kyrgyzstan	NZ	New Zealand	ZW	Zimbabwe
CI	Côte d'Ivoire	KP	Democratic People's Republic of Korea	PL	Poland		
CM	Cameroon	KR	Republic of Korea	PT	Portugal		
CN	China	KZ	Kazakhstan	RO	Romania		
CU	Cuba	LC	Saint Lucia	RU	Russian Federation		
CZ	Czech Republic	LI	Liechtenstein	SD	Sudan		
DE	Germany	LK	Sri Lanka	SE	Sweden		
DK	Denmark	LR	Liberia	SG	Singapore		
EE	Estonia						

5

VASCULAR ACCESS SYSTEMS FOR HEMODIALYSIS

BACKGROUND OF THE INVENTION

10 Currently, HD (hemodialysis) and vascular access for chemotherapy and plasmapheresis is achieved in one of several ways. Applicant's invention involves a new method and instrumentation for HD and vascular access designed to eliminate the problems of the prior methods and create a new, more durable, easier to use, vascular access system.

15 One prior art method involves a primary arteriovenous fistula. In this method, a native artery is sewn to a native vein creating a high flow system of blood in a vein which over time can be accessed with two hemodialysis needles attached to a dialysis machine. The problem with this method is that few patients are candidates secondary to anatomy and in others the veins or shunt fail to enlarge and mature properly even if the primary fistula remains patent. These arteriovenous
20 fistulas also become aneurysmal over time requiring revision.

Another method involves a subcutaneous prosthetic conduit (PTFE) in the shape of a tube which is sewn at either end to openings made in an artery and vein. This method causes recurrent stenosis at the venous outflow leading to thrombosis (i.e., graft closure) secondary to intimal hyperplasia at venous anastomosis.
25 Thrombosis also occurs at needle puncture sites along the PTFE.

Another method involves a "tunneled" percutaneous dual lumen catheter which is inserted into a central vein. This causes recurrent thrombosis secondary to stasis of blood in the lumen (i.e., not a continuous flow system like an A-V fistula) and build up of fibrinous debris at the venous end. Further, the access end of the
30 catheter protrudes through the skin making it cosmetically unappealing, cumbersome to live with, as well as more likely to become infected.

A further method involves the use of the Sorenson Catheter. This is a percutaneous (not tunneled) dual lumen catheter, placed into the central venous system, which is used to provide temporary access for the purposes of hemodialysis.
35 These catheters are prone to kinking, clotting, infection, and poor flow rates.

5 A still further method of vascular access involves the "Port-a-cath". This system of venous access, which utilizes a subcutaneous reservoir attached to a central venous catheter, is used for long term intervenous access for chemotherapy etc. (It is not intended for HD.) The ports are prone to clotting and must be continually flushed since they are a stagnant system.

10 Applicant's invention involves a vascular access system, known as the Squitieri Hemodialysis and Vascular Access System, which creates a continuous blood flow and which is easily accessed and resistant to clotting. These advantages provide ideal access for long term HD, chemo or blood draws. An example, would be patients who are on coumadin which require weekly blood draws. This new
15 system becomes less painful over time as the skin over the "needle access" site become less sensitive. The veins are spared repeated blood draws which results in vein thrombosis to such a degree that some patients "have no veins left" making routine blood draws impossible.

20 Among the more relevant prior art patents are U.S. patents 4,898,669; 4,822,341; 5,041,098; and, 4,790,826. None of the foregoing patents disclose a system having the features of this invention

SUMMARY OF THE INVENTION

25 A hemodialysis and vascular access system comprises a PTFE end which is sutured to an opening in an artery at one end and the other end is placed into a vein using any technique which avoids the need for an anastomosis between the silicone "venous" end of the catheter and the vein wall. The system comprises any material, synthetic or natural (i.e. vein) which can be sutured to the artery (i.e. preferably PTFE) at one end while the other end is composed of a material which is suitable
30 for placement into a vein in such a way that the openings in the "venous" end of the system are away from the site where the graft enters the vein. The system may also be constructed of multiple layers of materials i.e. PTFE on the inside with silastic on the outside. The "Needle Receiving Site" may also be covered with PTFE to encourage self sealing and tissue ingrowth.

5 A preferred embodiment comprises a combination of PTFE conduit sewn to
an artery on one end of the system with the other end connected to a silastic-plastic
catheter which can be percutaneously inserted into a vein via an introducer. The
venous end may also be placed via open cut down. The seal around the system
where it enters the vein may be "self sealing" when placed in percutaneous
10 technique; it may be achieved with a purse string when done by open technique "cut
down"; or, it may be sewn to the vein to create a seal with a "cuff" while the
system continues downstream within the venous system to return the arterial blood
away from the site of entry into the vein. The entire system can be positioned
subcutaneously at the completion of insertion. This design is a significant
15 improvement over existing methods because it avoids the most frequent complication
of current HD access methods. By utilizing an indwelling venous end, one avoids
creating a sewn anastomosis on a vein which is prone to stenosis secondary to
neointimal hyperplasia. By having continuous flow through the silastic end of the
catheter, thrombosis of these catheters can be avoided. Dialysis is made more
20 efficient by decreasing recirculation of blood which accompanies the use of side by
side dual lumen catheters inserted into a central vein. This invention not only
benefits the patient but it also speeds dialysis thus saving time and money.

To summarize, the Squitieri Access System comprises a tube composed of
PTFE and a silastic catheter. This tube is used to create an arteriovenous fistula.
25 The PTFE end (arterial end) of the tube is sewn to an artery while the silastic
catheter end is placed into the venous system by the Seldinger technique much like a
standard central line. The entire system is subcutaneous at the completion of
insertion. This system is a composite of the arterial end of a "gortex graft" joined
to the venous end of a "permacath". This system enjoys strengths of each type of
30 access and at the same time avoids their weaknesses.

Accordingly, an object of this invention is to provide a new and improved
vascular access system.

Another object of this invention is to provide a new and improved
hemodialysis and vascular access system including an easily replaceable needle
35 receiving site which has superior longevity and performance, is more easily

5 implanted, more easily replaced, and is "user friendly" i.e. easily and safely accessed by a nurse or patient which is ideal for home hemodialysis.

 A more specific object of this invention is to provide a new and improved Squitieri hemodialysis and vascular access system including a subcutaneous composite PTFE/Silastic arteriovenous fistula.

10 A further object of this invention is to provide a new and improved hemodialysis and vascular access system including a fistula utilizing an indwelling silastic end which is inserted percutaneously into the venous system and a PTFE arterial end which is anastomosed to an artery and including a unique needle receiving sites which are positioned anywhere between the ends and which have
15 superior longevity and performance.

 A further object of this invention is to provide a system constructed to preserve laminar flow within the system and at the venous outflow end to reduce turbulence and shear force in the vascular system to the degree possible.

20 A still further object of this invention is to provide a system wherein the arterial end (PTFE) may also be placed by percutaneous technique including one where blood entry holes are distant from the site where blood enters the veins.

5

BRIEF DESCRIPTION OF THE DRAWINGS

The above and other objects of this invention may be more clearly seen when viewed in conjunction with the accompanying drawings wherein:

- FIG. 1 is a perspective view of the vascular access system comprising the invention;
- 10 FIG. 2 is a cross-sectional view of the needle access site taken along the line 2-2 of FIG. 1;
- FIG. 3 is a cross-sectional view similar to FIG. 2 with a needle inserted into the access site;
- 15 FIG. 4 is a cross-sectional view of the coupling between the PTFE and the silicone venous end of the catheter;
- FIG. 5 is a perspective view of an alternate embodiment of the invention with one port having a tube sewn to a vein;
- FIG. 6 is a perspective view of the embodiment in FIG. 5 with a silastic tube floated down a vein;
- 20 FIG. 7 illustrates a ringed tube sewn to an artery and connected to a first access site which is joined to a second site by silastic tubing and includes an outflow through silastic tubing which is floated into the venous system;
- FIG. 8 is similar to FIG. 7 but shows PTFE sewn to an artery and silastic tubing floated into a different portion of the venous system;
- 25 FIG. 9 depicts ringed PTFE tubing sewn to the subclavian artery and a dual access site coupled to the venous system at its other end;
- FIG. 10 shows a multi-layered variation at the venous end of the system;
- FIG. 11 discloses a quick coupler design utilized in conjunction with the system;
- 30 FIG. 12 is a unique port design utilized in conjunction with the system;
- FIG. 13 shows holes where ports can be fixed in place while FIG. 13a and FIG. 13b show cross-sectional views which depict the internal construction of the invention with FIG. 13b illustrating multi-layered tubing; and,
- 35 FIG. 14 shows a variation of the system entry through vein wall (i.e. not percutaneous or purse string) wherein a cuff, sewn to vein as indwelling

5 portion, is floated down stream.

DETAILED DESCRIPTION OF THE INVENTION

10 Referring to the drawings the Squitieri hemodialysis and vascular system, as shown in FIG. 1, comprises a PTFE/dacron (or other synthetic or natural material) tube 10 of several centimeters in length which is attached at one end by means of a coupling ii to a needle access site 20. Adjustable band 18 regulates the blood flow through the access site 20. The PTFE tube 10 is approximately 7mm in diameter and transitions downward to an open end portion 19 approximately 4mm in diameter.

15 The access site 20 includes an in line aperture 16, see FIG. 2, having a silicone tube 41 connected thereto at one end leading to a long flexible plastic/silastic/silicone tube 12 with transverse holes 13 along its free end. The number of holes 13 may vary within predetermined limits to achieve optimum results. The end 36 may be beveled for ease of insertion. This tubular arrangement
20 functions as a subcutaneous connection between the arterial and venous systems. It may also be modified to allow part of the system to exit through the skin 14 to provide access to the blood circulation without placing needles 15 through the skin 14 into the fistula (usually at the PTFE end).

25 Along the length of the catheter specially constructed access segments 20 are located to receive specially designed needles 15 into the system to gain access to the blood stream which flows through aperture 16. This method avoids perigraft bleeding which leads to thrombosis either by compression of the graft by hematoma or by manual pressure applied to the graft in an attempt to control the bleeding.

30 The needle access areas 20 which are designed to receive needles 15 etc. to allow access to the system are in line conduits with self-sealing material 17 such as silicone located beneath the skin surface. The silicone member 25 comprises an oval configuration exposed within the frame 26 for ease of puncture. The system may be accessed immediately after insertion without having to wait for the graft to incorporate into the tissues as is the case with the current methods of subcutaneous
35 fistulas. These access areas 20 will protect the graft since they are uniformly and

5 easily utilized requiring little training or experience. The "needle receiving" sites 20 are designed in such a way to preserve laminar flow as far as possible (i.e. not a reservoir arrangement). Needle receiver sites 20 may be connected to a system via "quick couple" 45 for easy exchangeability, see FIG. 11.

10 FIGS. 2 and 3 disclose a needle access site 20 wherein a silicone member 25 is mounted within a plastic or metal frame 26. A protruding portion 27 of member 25 extends upwardly through the aperture 31 while a flange portion 28 extends outwardly on both sides of the portion 27 to be gripped by teeth 29 on the internal surface of frame 26 and member 32. The member 26 includes a passage 16 for blood flow. The blood flow is accessed by inserting needles 15 through the silicone 25 which is preferably oval in shape. The teeth 29 seal the arterial pressure. The internal chamber 16 of the needle receiving site 20 is tubular in shape.

15 The free end 19 of the PTFE tube 10 is sewn to an opening in an artery 30, see FIG. 7, while the plastic end 24 having been inserted percutaneously lies in the venous system in such a way that the openings 13 in the silastic tube 12 are downstream from the site where the flexible plastic tube 24 enters the vein 40. The venous end may be inserted via "cutdown". The purpose of the system is to allow communication between an artery 30 and a vein 40 in such a way that the system may be accessed by either puncturing the PTFE segment or by entering the specialized "needle receiving" site 20. This allows blood to flow from the system to a hemodialysis machine (not shown) and then return into the venous outflow portion at a more distal (venous end) location allowing the blood 35 to return from the HD machine (not shown) back into the patient.

25 FIG. 4 discloses, as an alternative, a "glued" connection between PTFE tubing 60 and silicone tubing 61 wherein the PTFE 61 is inserted into an enlarged portion of silicone 61 wherein the longitudinally extending portion includes a raised section 63 which locks a raised section 64 of PTFE 61 within the silicone 60.

30 In this invention, the materials used may vary as specified herein. The system may be constructed of one or more specific materials. The arteries and veins used may also vary. Material may also be covered with thrombus resistant

35

5 coatings (heparin, etc.) or biologic tissue. The system may in specific cases be "ringed" for support.

The same concept of using an arterialized venous access catheter may be applied to the use of long term indwelling catheters used to give chemotherapy etc., making the current ports obsolete as these new access systems will have a
10 decreased thrombosis rate and they will no longer need to be flushed as continuous blood flow through the system makes thrombus formation unlikely. This will definitely cut down on costs since it will decrease nursing requirements in out patient settings, etc.

In alternate embodiments shown in FIGS. 5 and 6, the system comprises an
15 arterial reservoir structure or port 50 with a needle accessible top portion 51 preferably-constructed of silicone. The reservoir 50 is connected to an outlet tube 53 of PTFE (gortex-ringed), which is sewn to an artery 30 at its other end. The venous outlet tube 52 is constructed in a similar way but it is either sewn to a vein 40 via gortex ringed portion 52 or is placed percutaneously into the central
20 circulation via an indwelling venous (silicon) catheter 42 as shown in FIG. 6. There is no continuous flow through this version of the system since the ports are not connected. Flow is established when the system is attached to an HD machine with a needle 15 in the arterial port 51a to deliver blood to the HD machine and a second needle 15 is placed in the venous port 51b to the vein 40 to deliver blood to the
25 patient. The ports 51a, 51b will remain flushed with heparin when not in use to avoid clotting when accessed through the skin 14 with needles 15. The ports 51a, 51b will also provide high flow access to both the arterial and venous systems. FIG. 6 shows two separate ports 51a and 51b with one tube 53 sewn to an artery 30 and the other tube 42 floated down a vein 40.

30 FIG. 7 illustrates in an anatomical drawing, a ringed gortex tubing 53 sewn to an artery 30 at 62 and coupled at its other end 63 to the needle access site 20. The site 20, see FIGS. 1-3, is joined by silastic tubing 64 to a second access site 20a which has an outlet silastic tube 65. The outlet tube 65 includes a plurality of perforations 66 at its outlet end which is positioned in the venous system 67 through
35 vein 40. Either site 20 or 20a can be used for needle access.

5 FIG. 8 depicts an embodiment similar to that of FIG. 7 except that the coupling between the artery 30 and the first needle access site 20 is PTFE tube 69. The entry to the venous system 67 is via vein 40 which has silastic tubing 65 floated therein. 69a depicts PTFE joining parts 20 and 20a.

10 FIG. 9 illustrates a dual needle access site 80 which is coupled via ringed PTFE 53 to the subclavian artery 30 and floated into the venous system 67 via silastic tubing 65. The dual site 80 provides additional access through 25a, 25b in approximately the same area with tubing (not shown) extending through the dual site 180.

15 FIG. 10 depicts a variation of the invention at the venous end wherein the outlet of the port 20 comprises PTFE tubing 91 located within a silastic catheter 92. This design is appropriate if thrombosis is a problem in the outlet silastic portion of the shunt.

20 FIG. 11 discloses a quick coupler 45 joining the PTFE tubing 53 to the port 46 in the needle access site 20. A plastic or metal member 47 includes a portion 48 which engages the cylindrical tubing 10, an intermediate portion 49 extending perpendicularly outward and an end portion 43 tapered outwardly at an angle and including an inward projection 44. The projecting portion 44 of the member 47 engages a slot 54 in the port 46 firmly fixing the PTFE 10 therebetween. 45a is made of flexible material to allow a gentle curve in tubing as it exits/enters port.

25 FIG. 12 is an exploded view of a new port embodiment wherein the port 71 comprises a frame 72 having an inlet 73 and an outlet 74. The plastic or metal frame 75 includes a recessed reservoir 76 and end walls 78a and 78b. An upper member 85 having a recess 86 and downwardly projecting sides 87a and 87b fits within walls 77a and 77b. The member 45 rapidly couples the PTFE tubing 10 to site 71 with tubing 88 which fits over the inlet coupling 73 and the outlet coupling 30 74 with recessed portions 75a and 75b which engage tubing 88a and 88b and have couplers 89a and 89b which slide over the tubing 88a, 88b to engage the couplings 73 and 74.

35 FIG. 13 shows a typical dual port system showing holes 55 where ports 20 can be fixed in place.

5 **FIG. 14 discloses a cuff 56 which is made of PTFE and sewn to a vein. No physiological/functional venous anastomosis is created as blood is returned at the end of the system distant from the cuff. The silastic end 12 may still be lined with PTFE.**

10 **The upper member 86 includes an oval silicone access site 90 with an outer housing 91 which includes an aperture 92 surrounds the silicone oval 90. This embodiment provides a quick assembly for a needle access site 71.**

15 **The Squitieri Hemodialysis/Vascular Access System avoids creation of a venous anastomosis, a revolutionary advancement, i.e. there is no site for neointimal hyperplasia at a venous anastomosis which accounts for the vast majority of PTFE arteriovenous graft failures (60-80%). This is accomplished by returning the blood into a larger vein via an indwelling venous catheter 42. The site of blood return to the venous system is not fixed to the vein wall where neointimal hyperplasia occurs with the standard PTFE bridge graft. This feature represents a tremendous advantage over the present grafts.**

20 **As a further advantage, the system is not stagnant and prone to thrombosis, i.e. constant flow through the new system avoids the problem of clotting inherent in indwelling dual lumen venous catheters which remain stagnant when not in use. It also avoids need to flush catheters with heparin thereby reducing nursing costs to maintain the catheter.**

25 **The Squitieri system avoids externalization of components which are prone to infection. Since dual lumen catheters exit the skin 14, they frequently lead to sepsis requiring catheter removal despite subcutaneous tunneling. This new access is entirely subcutaneous.**

30 **Very importantly the system proposed herein, avoids problems with the aspiration of blood from the venous system and "positional" placement through continuous flow. A frequent problem with dual lumen catheters is their inability to draw blood from the venous system due to clot and fibrinous debris ball-valving at the tip of a catheter. This new system receives blood directly from arterial inflow which ensures high flow rates needed for shorter, more efficient dialysis runs. It**
35 **also avoids the frequent problem of the catheter tip "sucking" on the vein wall**

5 inhibiting flow to the dialysis machine and rendering the access ineffective.

 The system avoids recirculation seen with dual lumen catheters resulting in more efficient and more cost effective dialysis.

 The system avoids the need for temporary access with incorporation of "Needle Access Sites" 20. A-V fistulas and gortex grafts must "mature" for several weeks before use. This creates a huge strain on the patient as well as the doctor to achieve temporary access while waiting to use the permanent access. Temporary access is very prone to infection, malfunction and vein destruction. By placing sites 20 designed to receive needles 15 along the new access, the system may be used the day it is inserted.

15 The system avoids PTFE needle site damage with the incorporation of "Needle Access Sites" 20. Needle access directly into PTFE is presently uncontrolled and user dependent. Often, PTFE is lacerated by access needles. While this system may be accessed via the PTFE segment, the needle receiving sites are the preferred method. This leads to excessive bleeding which requires excessive pressure to halt the bleeding causing thrombosis of the graft. "Needle Access Sites" 20 on the Squitieri access system allow safe, quick, and easy entry into the system and avoid the complications inherent in placing needles directly into PTFE. It also avoids perigraft bleeding which will compress and thrombose the graft. By eliminating the long time needed to compress bleeding at the needle site, the system shortens dialysis runs.

25 The Squitieri system permits an easier, faster insertion technique. Only one anastomosis at the arterial end and a percutaneous placement of the venous end is required. A modification allows the system to be sutured to the vein wall while the system tubing is floated down stream from this site where the system enters the vein 30 40. This saves operating room time at thousands of dollars per hour. The technique is easier with faster replacement. It avoids difficult and time consuming revision of venous anastomosis required to repair venous outflow occluded by neointimal hyperplasia. If the system malfunctions, the silastic catheter end 65 slips out easily and the arterial PTFE end 53 is thrombectomized. New access sewn to 35 the thrombectomized PTFE at the arterial end and the silastic venous end is replaced

5 percutaneously via Seldinger technique or "open technique".

 The end result of the above advantages translates into superior patency rates and a decreased complication rate with this new system. Patients are spared the repeated painful hospitalizations for failed access as well as the emotional trauma associated with this difficult condition. The physicians are spared the dilemma of
10 how to best treat these patients. This system will have a large impact on the current practice of vascular access in areas such as hemodialysis; plasmapheresis; chemotherapy; hyperalimentation; and chronic blood draws.

 While the invention has been explained by a detailed description of certain specific embodiments, it is understood that various modifications and substitutions
15 can be made in any of them within the scope of the appended claims which are intended also to include equivalents of such embodiments.

CLAIMS

What is claimed, is:

1. A Squitieri hemodialysis and vascular access system which shunts blood between a vein and an artery and provides needle access comprising:

5 PTFE tubing connected to an artery at one end;
silicone tubing inserted within a vein at one end and including a plurality of apertures extending through the silicone tubing at said end; and,
a needle access port having a frame including a conduit extending therethrough, said frame having an inlet connected to the other end of the
10 PTFE tubing and an outlet connected to the other end of the silicone tubing to provide a flow path for blood and a silicone member protruding from the frame to provide access for needles into the flow path.

2. A Squitieri hemodialysis and vascular access system which shunts blood between a vein and an artery and provides needle access in accordance with Claim
15 1, wherein:

the needle access port includes an outer frame member having an upper surface including an aperture extending therethrough and downwardly extending walls about its periphery having inlet and outlet apertures, wherein the upper surface includes a lower portion having a plurality of teeth;
20 a silicone member mounted within the frame having a surface engaged by the frame teeth and an upwardly protruding portion extending through the frame aperture; and,
a second frame member having a transverse conduit extending between the inlet and outlet apertures, an upper surface having a plurality of
25 teeth engaging the silicone member to effect a seal and wherein the second frame member is positioned within the walls of the first frame member.

3. A Squitieri hemodialysis and vascular access system which shunts blood between a vein and an artery and provides needle access in accordance with Claim

1, wherein:

the protruding silicone member has an oval configuration.

4. A Squitieri hemodialysis and vascular access system which shunts blood between a vein and an artery and provides needle access in accordance with Claim

5

1, wherein:

the PTFE tubing includes rings mounted thereabout to provide additional strength.

5. A Squitieri hemodialysis and vascular access system which shunts blood between a vein and an artery and provides needle access in accordance with Claim

10

1, wherein:

a second needle access port having an inlet and an outlet and silastic tubing coupling the inlet of the second needle access port with the outlet of the other needle access port and wherein the outlet of the second access port is coupled to the silicone tubing, said tubing being floated within a vein at its other end.

15

6. A Squitieri hemodialysis and vascular access system which shunts blood between a vein and an artery and provides needle access in accordance with Claim

1, wherein:

the PTFE tubing is sewn to an artery at one end and coupled to the access port at the other end; and,

20

the silicone tubing is coupled to the needle access port at one end and is floated within a vein at the other end.

7. A Squitieri hemodialysis and vascular access system which shunts blood between a vein and an artery and provides needle access in accordance with Claim

25

1, wherein:

the PTFE tubing is inserted within an outer silicone tubing at the inlet to the needle access port.

8. A Squitieri hemodialysis and vascular access system which shunts blood between a vein and an artery and provides needle access in accordance with Claim 1, further including:

an adjustable band mounted about the PTFE tubing at the inlet to the needle access port to regulate blood flow.

9. A Squitieri hemodialysis and vascular access system which shunts blood between a vein and an artery and provides needle access in accordance with Claim 5, wherein:

a second needle access port is mounted to the needle access port, said ports having a single frame and a conduit extending longitudinally therethrough to the outlet tubing.

10. A Squitieri hemodialysis and vascular access system which shunts blood between a vein and an artery and provides needle access in accordance with Claim 1, further including:

a quick coupler for joining the PTFE tubing to the needle access port comprising a port member projecting outwardly from the frame inlet and having a circumferential slot extending thereabout, a cooperating member having an outer portion extending concentrically with the PTFE tubing and a portion extending outwardly therefrom and an outwardly sloped portion extending over the projecting port member and having an inner circumferential projection which engages the circumferential slot, and wherein the tubing extends over the port member to be engaged by the projecting portion of the cooperating member within the slot and a removable coupling which snaps over the cooperating member forcing it into a sealed engagement with the port member.

11. A Squitieri hemodialysis and vascular access system which shunts blood between a vein and an artery and provides needle access in accordance with Claim

1, wherein:

the needle access port comprises a first member having a base, walls extending upwardly therefrom to form an enclosed area, and outwardly extending couplings on opposite walls thereof at the inlet and outlet of said port;

a second member having a top including an upper aperture, downwardly extending side walls engaging the walls of the first member and having a conduit extending from the inlet to the outlet and a silicone member projecting from the upper aperture to provide needle access; and,

a tube mounted over each coupling and a coupler which fits over each tube to seal the tubes to the couplings.

12. A Squitieri hemodialysis and vascular access system which shunts blood between a vein and an artery and provides needle access in accordance with Claim 1, wherein:

the silicone tubing is floated within a vein at the one end and the plurality of apertures in the tubing are distant from the site where the tubing is inserted into the vein, said tubing not being fixed to the vein wall.

13. A Squitieri hemodialysis and vascular access system which shunts blood between a vein and an artery and provides needle access comprising:

an arterialized indwelling venous catheter having a portion coupled to an artery at one end and a portion inserted within a vein at the other end, said inserted vein portion having openings within the vein itself which are distant from the site of insertion wherein blood flows from an artery through the catheter and is returned to the vein through the openings thereby providing laminar blood flow from an artery to a vein.

14. A Squitieri hemodialysis and vascular access system which shunts blood between a vein and an artery and provides needle access in accordance with Claim 12 further including:

needles which are coupled to a hemodialysis system, said needles having been inserted directly into the catheter to shunt the blood flow.

15. A Squitieri hemodialysis and vascular access system which shunts blood between a vein and an artery and provides needle access in accordance with Claim 1 wherein:

the tubing comprises multiple layers.

16. A Squitieri hemodialysis and vascular access system which shunts blood between a vein and an artery and provides needle access in accordance with Claim 1 wherein:

the tubing and access port are placed percutaneously.

17. A Squitieri hemodialysis and vascular access system which shunts blood between a vein and an artery and provides needle access in accordance with Claim 1 wherein:

the silicone tubing coupled to the port inlet at one end includes an enlarged portion at the other end wherein the PTFE tubing which is connected to an artery at one end includes an enlarged portion at the other end and is inserted into the PTFE tubing to form a connection.

18. The method of shunting blood between a vein and an artery using the Squitieri hemodialysis and vascular access system comprising the steps of:

providing an access port;

sewing PTFE tubing to an artery at one end, the other end of said PTFE tubing being connected to the access port;

providing means to insure a laminar flow of blood through the access port;

inserting silicone tubing from the outlet of the access port into a vein;

and,

floating the silicone vein tubing down a vein, said tubing having

transverse apertures at its distal end said end being spaced from the insertion site.

- 5 19. The method in accordance with Claim 18 further including the steps of:
 providing a hemodialysis system with a needle coupling; and,
 inserting the needle into the access port to provide a blood flow to the
 hemodialysis system.
20. The method in accordance with Claim 19 wherein:
 the PTFE tubing, the silicone tubing and the access port are placed
 subcutaneously.

1/8

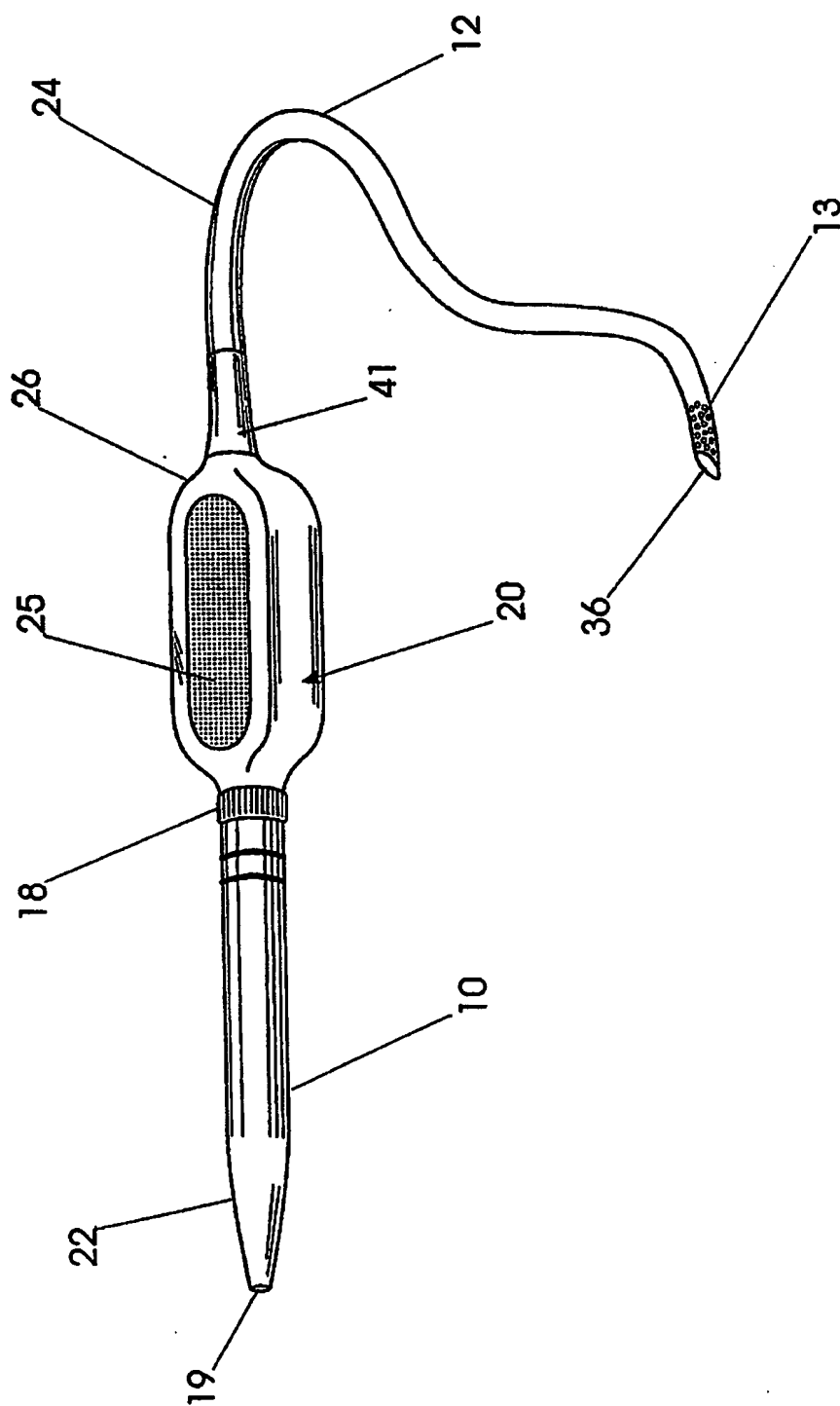


FIG. 1

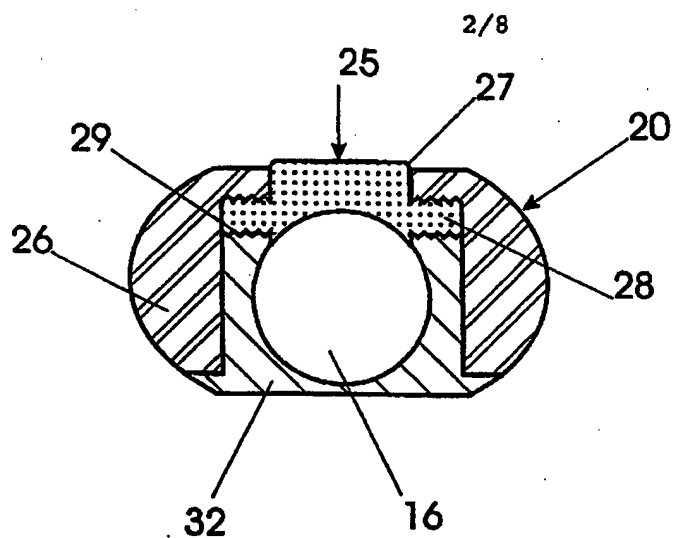


FIG. 2

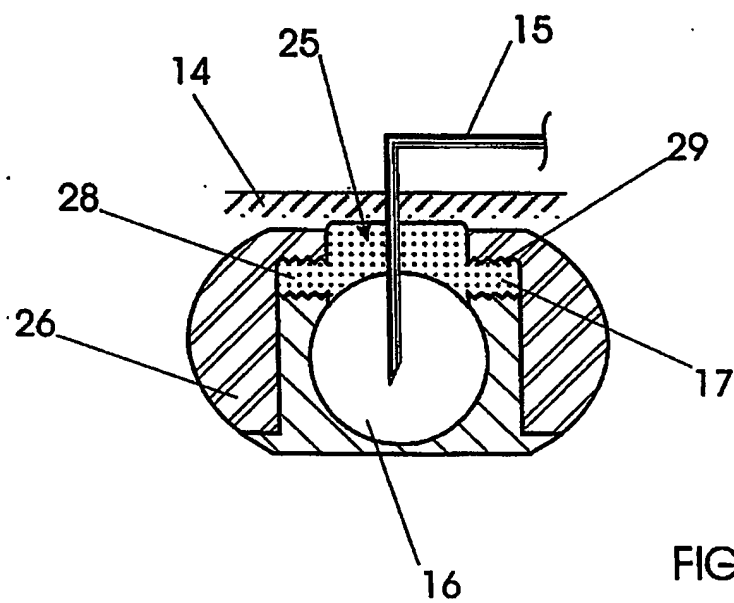


FIG. 3

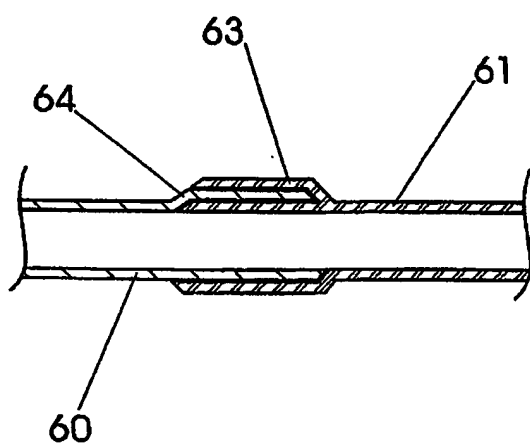


FIG. 4

FIG. 5

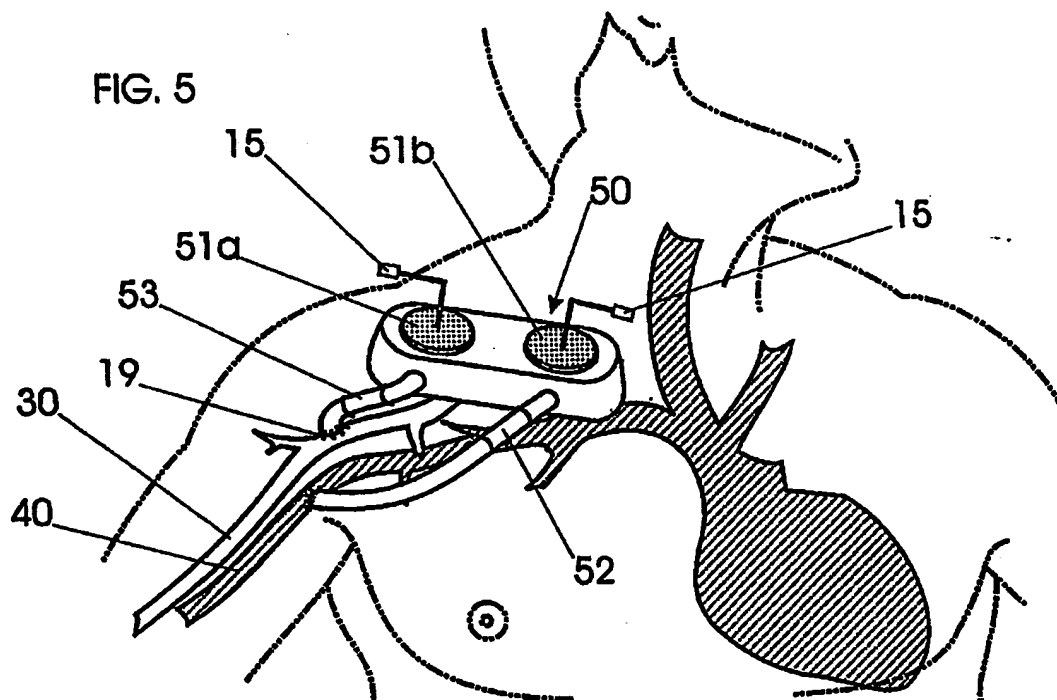
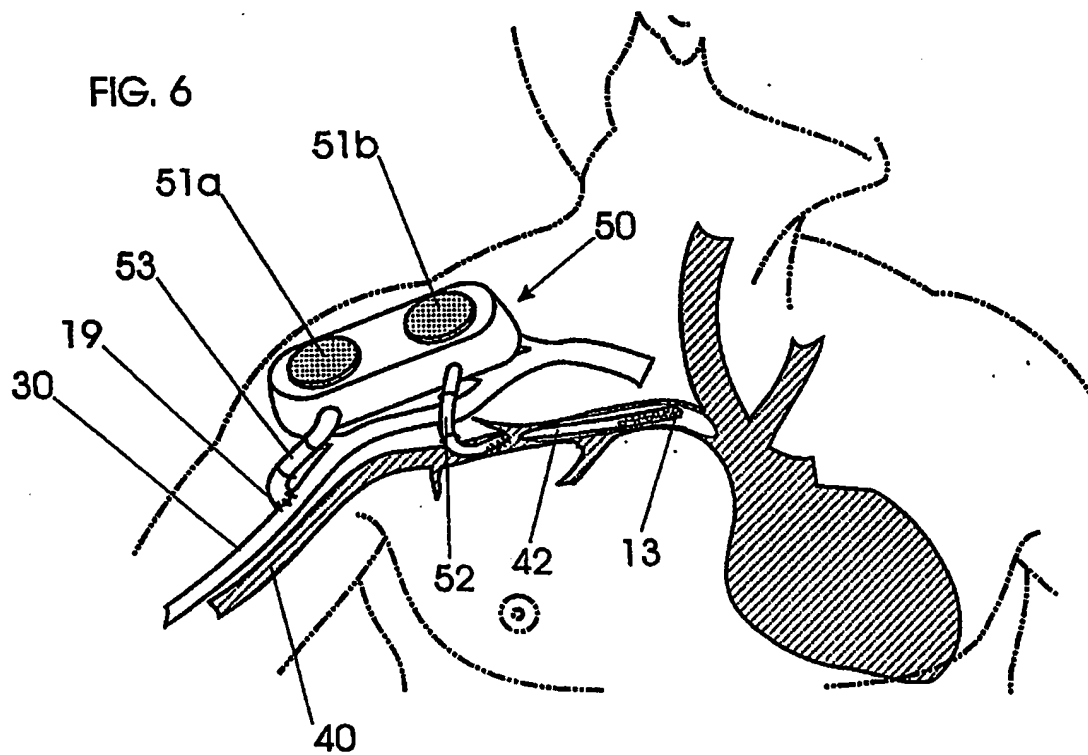


FIG. 6



4/8

FIG. 7

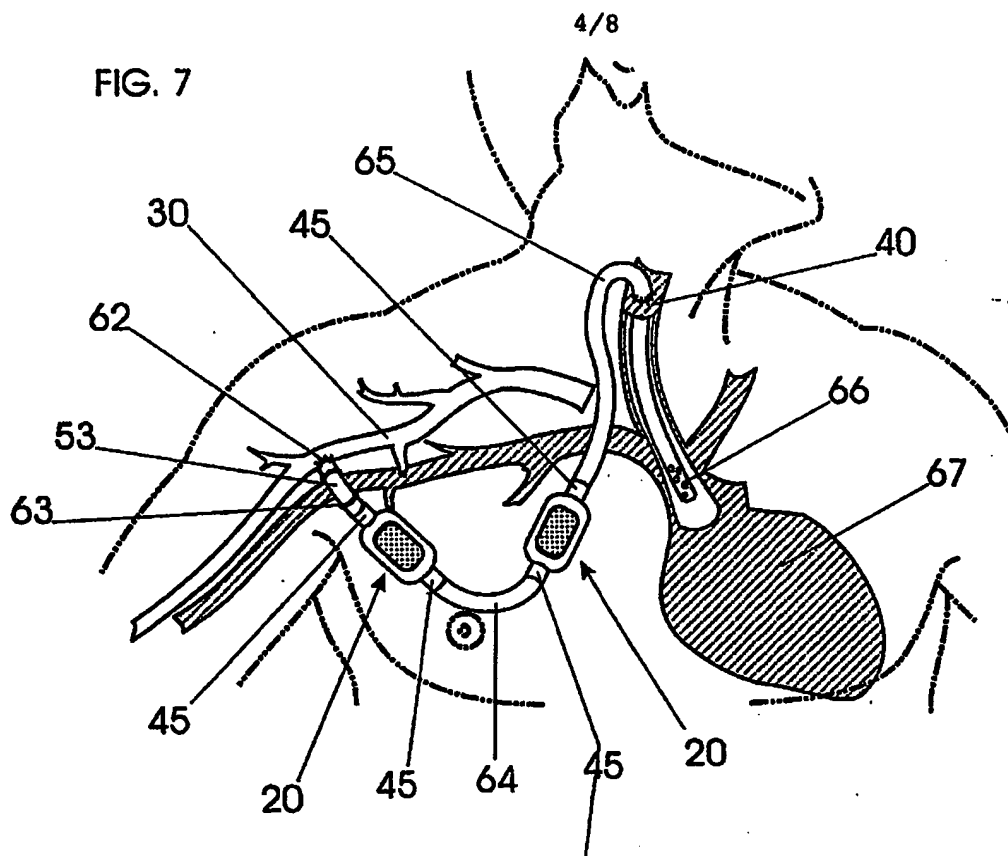


FIG. 8

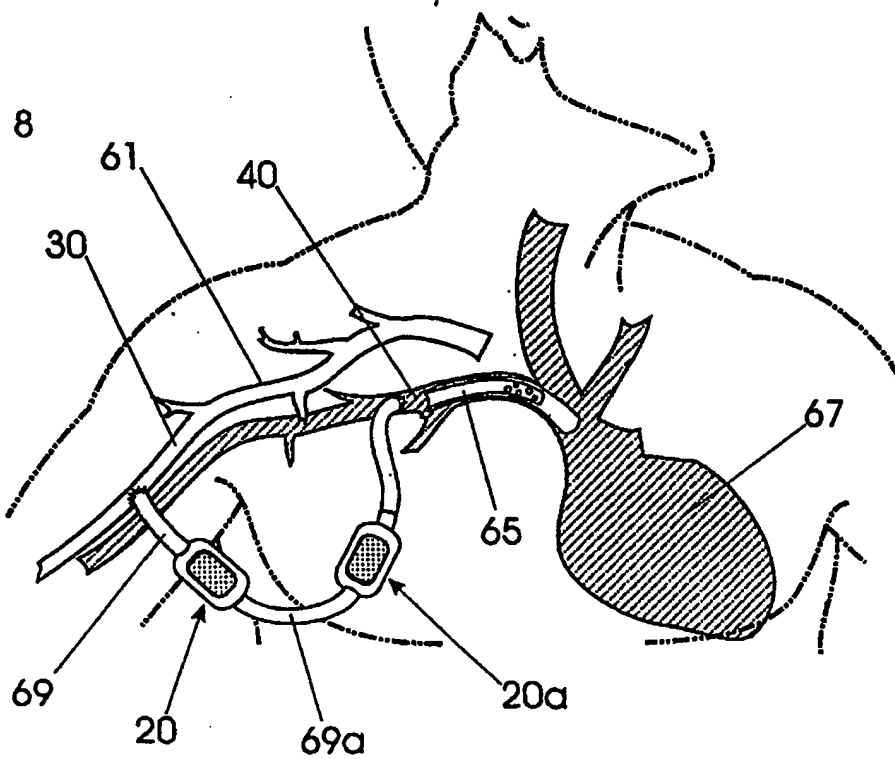
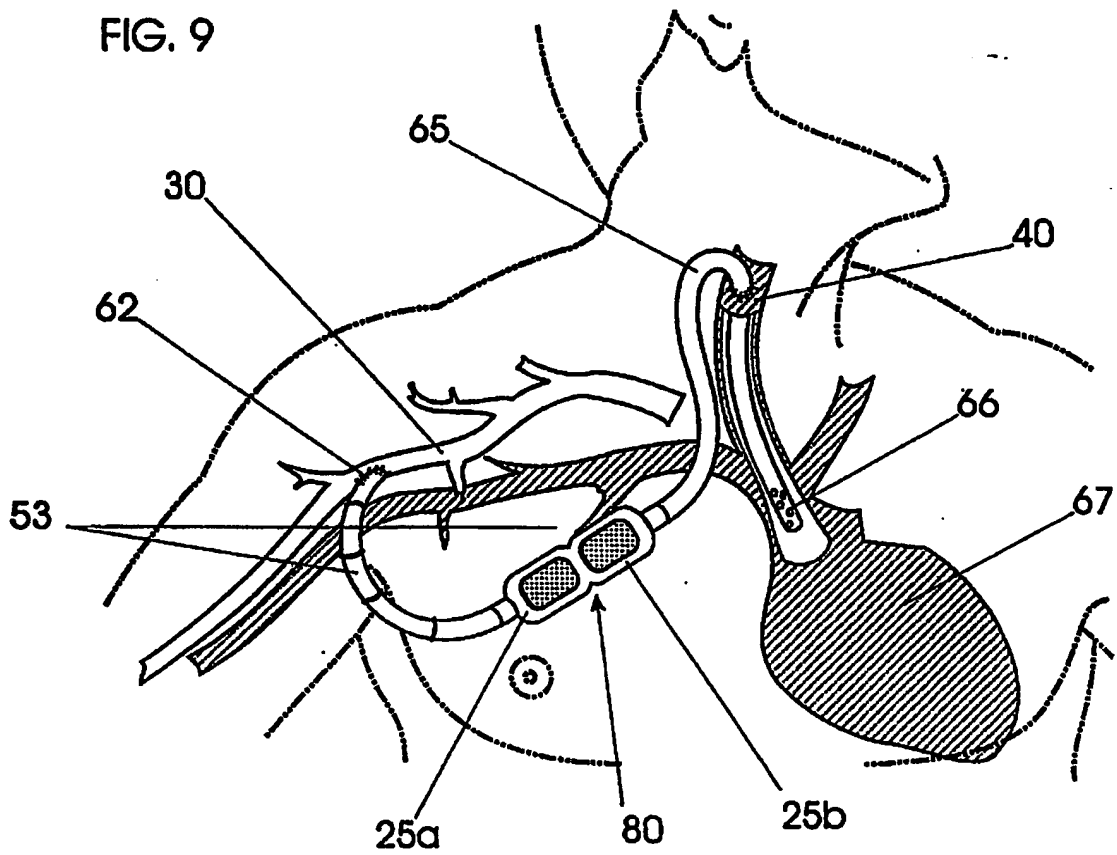


FIG. 9



6/8

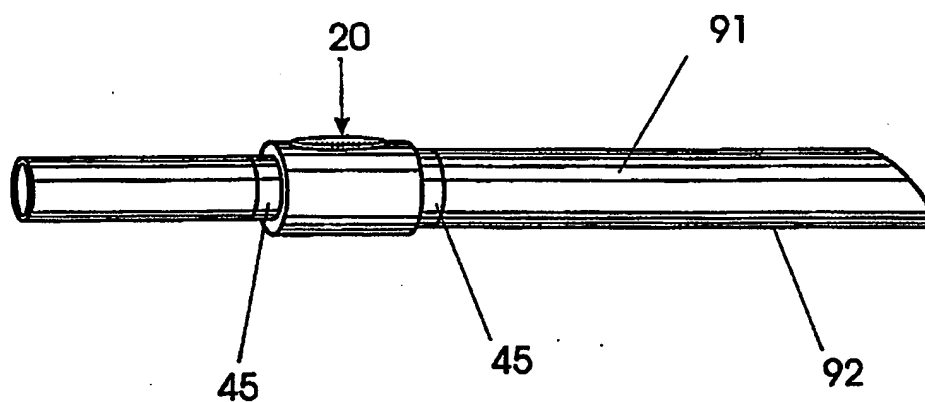


FIG. 10

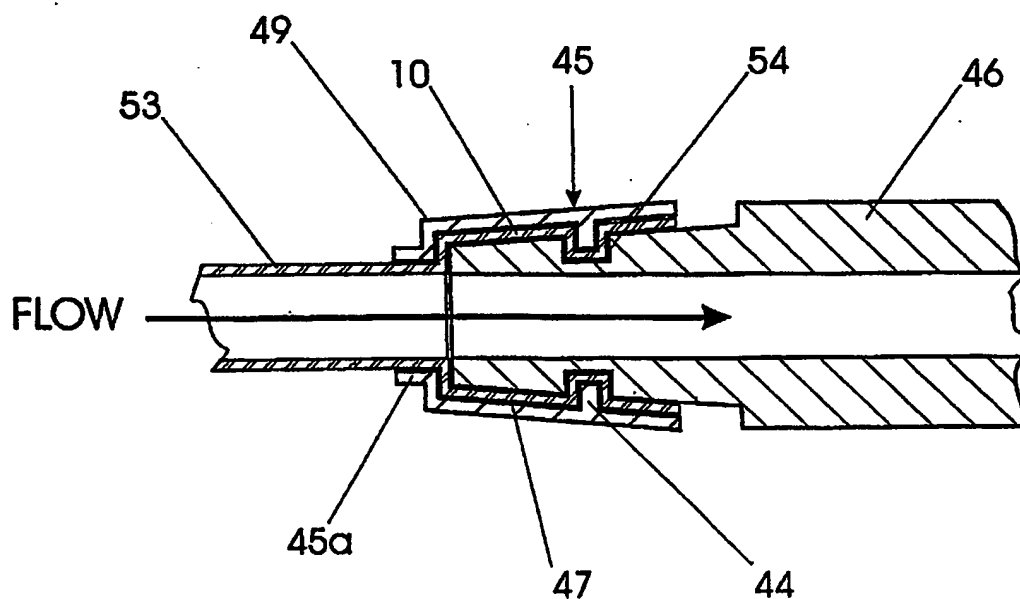


FIG. 11

7/8

FIG. 12

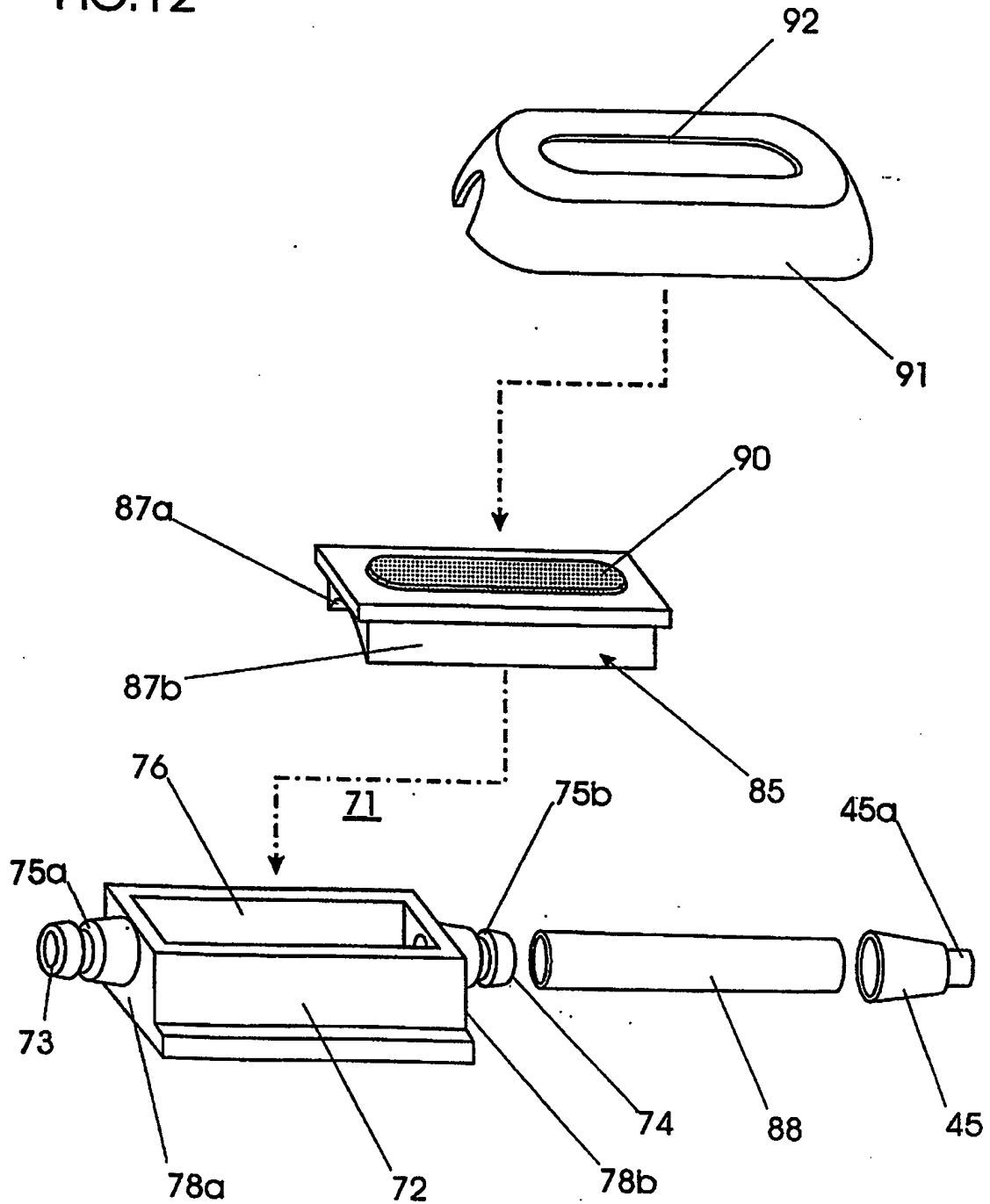


FIG. 13

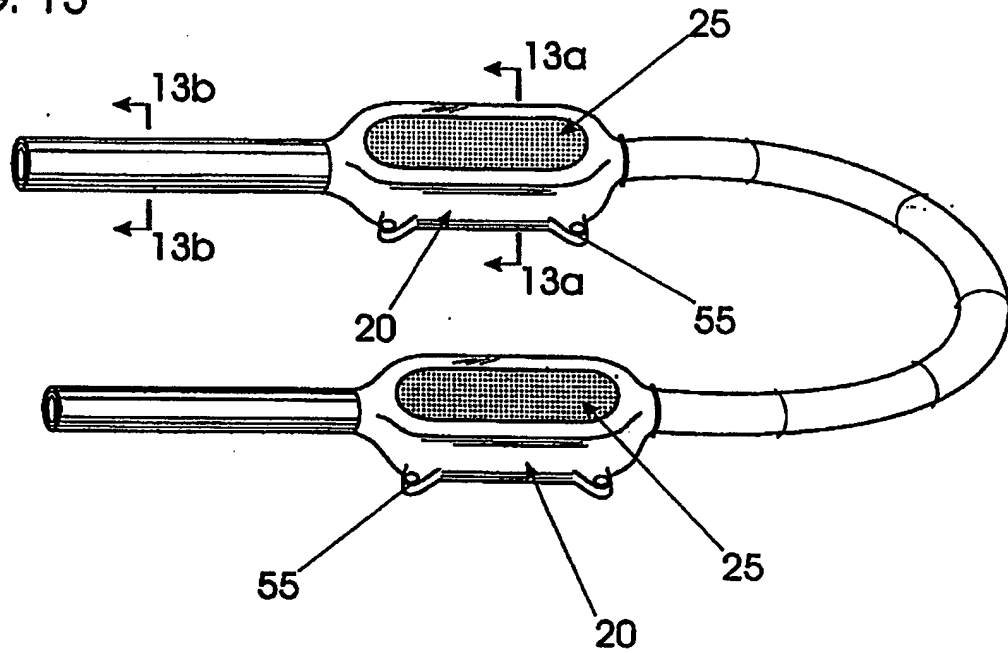


FIG. 13a

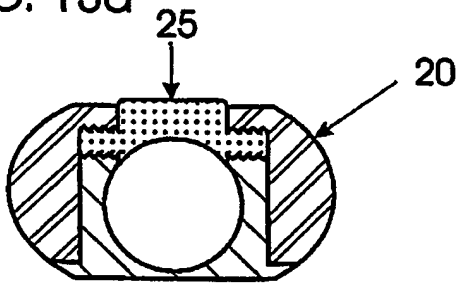


FIG. 13b

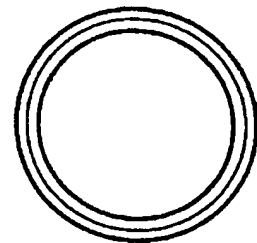
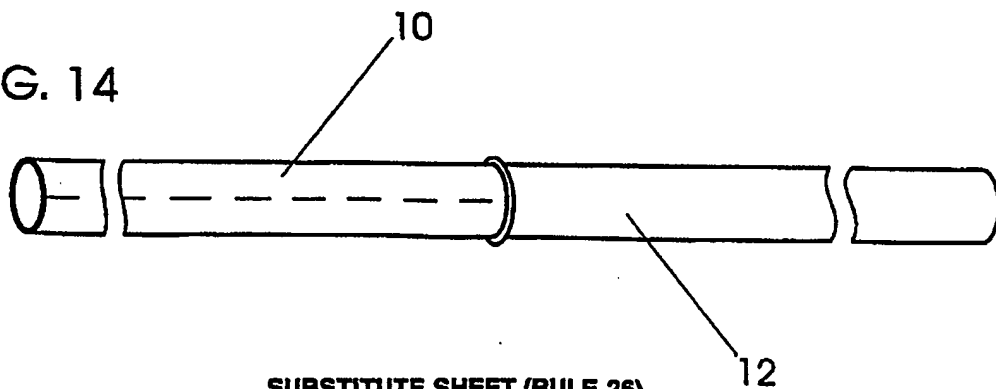


FIG. 14



INTERNATIONAL SEARCH REPORT

Int. Application No
PCT/US 98/01939

A. CLASSIFICATION OF SUBJECT MATTER IPC 6 A61M39/02 A61M39/10		
According to International Patent Classification (IPC) or to both national classification and IPC		
B. FIELDS SEARCHED Minimum documentation searched (classification system followed by classification symbols) IPC 6 A61M		
Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched		
Electronic data base consulted during the international search (name of data base and, where practical, search terms used)		
C. DOCUMENTS CONSIDERED TO BE RELEVANT		
Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	US 5 041 098 A (LOITERMAN DAVID A ET AL) 20 August 1991 cited in the application see abstract; figures 1-4A see column 4, line 56 - column 6, line 49 ---	1,12
A	DE 44 18 910 A (KOUDAIMI MOUHAMED KAMAL DR MED) 7 December 1995 see abstract; figures see column 1, line 1 - line 46 ---	1,12
A	US 4 447 237 A (FRISCH ELDON E ET AL) 8 May 1984 see abstract; figures see column 3, line 63 - column 4, line 62 see column 11, line 45 - column 12, line 8 -----	1,12
<input type="checkbox"/> Further documents are listed in the continuation of box C. <input checked="" type="checkbox"/> Patent family members are listed in annex.		
* Special categories of cited documents : "A" document defining the general state of the art which is not considered to be of particular relevance "E" earlier document but published on or after the international filing date "L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified) "O" document referring to an oral disclosure, use, exhibition or other means "P" document published prior to the international filing date but later than the priority date claimed "T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention "X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone "Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art. "Z" document member of the same patent family		
Date of the actual completion of the international search 24 April 1998		Date of mailing of the international search report 06.05.98
Name and mailing address of the ISA European Patent Office, P.B. 5818 Patentlaan 2 NL - 2280 HV Rijswijk Tel. (+31-70) 340-2040, Tx. 31 651 epo nl, Fax: (+31-70) 340-3016		Authorized officer Zeinstra, H

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US 98/01939

Box I Observations where certain claims were found unsearchable (Continuation of Item 1 of first sheet)

This International Search Report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:

1. ☒ Claims Nos.: 17-19
because they relate to subject matter not required to be searched by this Authority, namely:
Rule 39.1(iv) PCT - Method for treatment of the human or animal body by surgery
2. ☐ Claims Nos.:
because they relate to parts of the International Application that do not comply with the prescribed requirements to such an extent that no meaningful International Search can be carried out, specifically:
3. ☐ Claims Nos.:
because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

Box II Observations where unity of invention is lacking (Continuation of Item 2 of first sheet)

This International Searching Authority found multiple inventions in this International application, as follows:

1. ☐ As all required additional search fees were timely paid by the applicant, this International Search Report covers all searchable claims.
2. ☐ As all searchable claims could be searched without effort justifying an additional fee, this Authority did not invite payment of any additional fee.
3. ☐ As only some of the required additional search fees were timely paid by the applicant, this International Search Report covers only those claims for which fees were paid, specifically claims Nos.:
4. ☐ No required additional search fees were timely paid by the applicant. Consequently, this International Search Report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.:

Remark on Protest

- ☐ The additional search fees were accompanied by the applicant's protest.
- ☐ No protest accompanied the payment of additional search fees.

INTERNATIONAL SEARCH REPORT

Information on patent family members

Int. Appl. No.

PCT/US 98/01939

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
US 5041098 A	20-08-91	AT 130201 T	15-12-95
		AU 630970 B	12-11-92
		AU 5740790 A	18-12-90
		CA 2033161 A	20-11-90
		DE 69023646 D	21-12-95
		DE 69023646 T	02-05-96
		EP 0472618 A	04-03-92
		ES 2081988 T	16-03-96
		JP 6075596 B	28-09-94
		JP 4507050 T	10-12-92
		WO 9014118 A	29-11-90
		US 5129891 A	14-07-92
DE 4418910 A	07-12-95	NONE	
US 4447237 A	08-05-84	NONE	

**This Page is Inserted by IFW Indexing and Scanning
Operations and is not part of the Official Record**

BEST AVAILABLE IMAGES

Defective images within this document are accurate representations of the original documents submitted by the applicant.

Defects in the images include but are not limited to the items checked:

- ☐ **BLACK BORDERS**
- ☐ **IMAGE CUT OFF AT TOP, BOTTOM OR SIDES**
- ☐ **FADED TEXT OR DRAWING**
- ☐ **BLURRED OR ILLEGIBLE TEXT OR DRAWING**
- ☐ **SKEWED/SLANTED IMAGES**
- ☐ **COLOR OR BLACK AND WHITE PHOTOGRAPHS**
- ☐ **GRAY SCALE DOCUMENTS**
- ☐ **LINES OR MARKS ON ORIGINAL DOCUMENT**
- ☐ **REFERENCE(S) OR EXHIBIT(S) SUBMITTED ARE POOR QUALITY**
- ☐ **OTHER:** _____

IMAGES ARE BEST AVAILABLE COPY.

As rescanning these documents will not correct the image problems checked, please do not report these problems to the IFW Image Problem Mailbox.